

UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA ex rel.  
SUSAN HUTCHESON and PHILIP BROWN,

Plaintiffs,

v.

BLACKSTONE MEDICAL, INC. and  
ORTHOFIX INTERNATIONAL N.V.,

Defendants.

Civil Action No. 1:06-cv-11771-WGY

**BLACKSTONE MEDICAL INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS  
MOTION TO DISMISS RELATORS' COMPLAINT WITH PREJUDICE**

Pursuant to Rules 12(b) and 9(b) of the Federal Rules of Civil Procedure, Defendant Blackstone Medical, Inc. hereby files this memorandum of law in support of its motion to dismiss the complaint filed by Relators Susan Hutcheson and Philip Brown ("Complaint").

**I. SUMMARY OF ARGUMENT**

Relators' Complaint is jurisdictionally barred and fails to state a claim for which this Court can grant any relief. Relators Susan Hutcheson and Philip Brown ("Relators"), allege that Defendant Blackstone Medical, Inc. ("Blackstone") violated the federal False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA") by entering into purportedly improper consulting agreements and other kickback arrangements with physicians throughout the United States, which illegally induced those physicians to use Blackstone products in spinal surgeries. Relators further allege that as a result of the illegally-induced use of Blackstone products in surgeries, hospitals across the country submitted false claims for reimbursement to federally-funded government healthcare programs, including Medicare. (Compl. ¶¶ 1, 15.) However, these essential allegations have

been raised in other complaints before Relators here filed their Complaint. Consequently, the Court is without jurisdiction to hear the case based on the first-to-file rule and the public-disclosure bar. Furthermore, the Complaint fails to state any cognizable FCA claim. Indeed, Relators have made sweeping allegations of nationwide fraud, purportedly involving an untold number of hospitals and physicians over an unknown period of time, as to which they claim they have no first-hand knowledge. Not only does the Complaint fail to meet Rule 9(b)'s pleading standard, but it also fails to allege a wrongful discharge claim. For all these reasons, the Court must dismiss Relators' Complaint.

The Complaint is barred by the FCA's first-to-file rule. *See* 31 U.S.C. § 3730(b)(5). More than five months before Relators here filed suit against Blackstone, Relator John Thomas filed a *qui tam* complaint against Blackstone in the Eastern District of Arkansas, similarly alleging the use of improper consulting agreements and other purportedly unlawful kickbacks to induce physicians to use Blackstone products and cause hospitals to submit false claims for reimbursement to the federal government. Because the first-to-file rule bars subsequent suits based on the same allegations, Relators here are prohibited from bringing this action and this Court therefore lacks jurisdiction under the FCA to hear the suit. *See e.g., U.S. ex rel. Hampton v. Columbia/HCA Healthcare Corp.*, 318 F.3d 214 (D.C. Cir. 2003). Consequently, the Court must dismiss Relators' Complaint.<sup>1/</sup>

Relators' Complaint is also barred pursuant to 31 U.S.C. § 3730(e)(4)(A) because the claims are based upon publicly-disclosed facts. The "public disclosure" bar prohibits relators from bringing claims based upon publicly disclosed facts that describe the same "general

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<sup>1/</sup> The first-to-file bar supports the transfer of this action to the Eastern District of Arkansas where the *Thomas* action is pending. Although the Defendants have a motion to transfer pending, Blackstone is filing this Motion pursuant to the Court's order requiring Defendants to respond to the Complaint by May 14, 2009.

practice” alleged in other complaints. *See, e.g., U.S. ex rel. Settlemire v. D.C.*, 198 F.3d 913, 919 (D.C. Cir. 1999). Relators filed this Complaint more than a year after a civil complaint alleging the same general scheme of supposedly unlawful consulting agreements was filed in Florida, where Relators reside, and the FBI allegedly investigated that conduct, according to the Complaint.

And if the first-to-file and public disclosure bars were not enough to defeat Relators’ attempt to invoke the Court’s jurisdiction, the Complaint also falls woefully short of pleading a scheme under the FCA.

The submission of a false claim is indispensable to liability under the FCA and yet the Complaint neglects to mention even a *single* instance where such a supposedly false claim was made. A false claim is the *sine qua non* of an FCA violation. *See U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004) (overruled on other grounds). Relators’ Complaint fails to plead the submission of a false claim or fraudulent conduct that was material to the government’s decision to pay a claim or to plead other allegations of fraud with the particularity required by Rule 9(b).

Additionally, Plaintiff Hutcheson’s retaliatory discharge claim should be dismissed because it fails to state a claim. Hutcheson fails to allege any nexus between conduct protected under 31 U.S.C. § 3730(h) and her dismissal. Notably, upon her separation in 2006, Hutcheson entered into an agreement releasing Blackstone of all potential claims; that release applies to personal claims asserted on her behalf in the Complaint.

Because this Complaint is jurisdictionally barred and because Counts I and II fail to state a claim under the applicable laws, this Complaint should be dismissed with prejudice.

## **II. BACKGROUND**

### **A. Parties and Procedural History**

On September 27, 2006, Relators Hutcheson and Brown filed this *qui tam* action under seal. Hutcheson, a former Blackstone Regional Manager, and Brown, an independent distributor of Blackstone products, alleged in general and conclusory terms, that Blackstone violated the FCA by inducing physicians to utilize Blackstone's spinal surgery products through payment of kickbacks. (Compl. ¶¶ 1, 15.) Relators further alleged that since the use of Blackstone products was illegally-induced, hospitals across the country were caused to submit false claims for reimbursement for surgeries involving Blackstone devices. (Compl. ¶¶ 1, 15.) On November 21, 2008, the government filed a notice that it was not intervening "at this time" and on November 24, 2008, the Complaint was unsealed.

Blackstone manufactures and distributes instruments and devices used in spinal surgery. (Compl. ¶ 13.) Blackstone, like all other medical device manufacturers, enters into consulting agreements with physicians who assist the company in developing useful products.

However, it is the hospitals, not the physicians, that purchase the medical devices that are used in medical procedures. Moreover, as described below, hospitals only bill federal healthcare programs specifically for such devices on an itemized basis in a few unusual cases. No such special case is described or alleged in the Complaint.

### **B. Medicare Payment Methodology**

Medicare pays hospitals a predetermined, fixed rate for inpatient services under a prospective payment system ("PPS") based upon the assigned diagnosis related group, or "DRG," applicable to the medical condition and treatment of each patient discharged from the hospital. 42 U.S.C. § 1395ww(d). Under PPS, Medicare does not pay separately for individual items used in a patient's care; rather, it pays one standard rate for the hospitalization – including

any medical devices used during the hospitalization – based on the assigned DRG. *See* 42 C.F.R. pt. 412; Medicare Claims Processing Manual, ch. 3 – Inpatient Hospital Billing, § 20A, *available at* <http://www.cms.hhs.gov/Manuals/IOM/list.asp> (last visited on May 12, 2009) (“Under PPS, hospitals are paid a predetermined rate per discharge for inpatient hospital services furnished to Medicare beneficiaries. Each type of Medicare discharge is classified according to a list of DRGs.”). In most cases, the DRG rate constitutes full payment for all items and services provided by the hospital, including medical devices. 42 C.F.R. § 412.2(b)(1) (“The prospective payment amount paid for inpatient hospital services is the total Medicare payment for the inpatient . . . costs . . . incurred in furnishing services covered by the Medicare program.”). Itemized bills for specific products or devices do not affect the amount the federal government pays a hospital for its services. 42 C.F.R. § 412.2(f).

### **III. ARGUMENT**

#### **A. Relators are Barred by the First-to-File Rule from Prosecuting this Declined Qui Tam Action.**

Blackstone, at great expense, has been defending itself against vague, general allegations that it caused false hospital claims to be submitted by paying kickbacks to physicians, just like those Relators have attempted to put at issue here, since April 2006. But under the FCA, “[w]hen a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.” 31 U.S.C. § 3730(b)(5). This bar, referred to as the first-to-file bar, “prevent[s] successive plaintiffs ‘from bringing related actions based on the same underlying facts.’” *U.S. ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1187 (9th Cir. 2001). Relators’ *qui tam* action stems from facts underlying an earlier *qui tam* filed by Relator John Thomas in the United States District Court, Eastern District of Arkansas on April 14, 2006 (“*Thomas Action*”). *U.S. ex rel. Thomas v.*

*Blackstone Med., Inc.*, Civ. No. 4:06-CV-000465-JHL (E.D. Ark.). This earlier filed *qui tam* alleges, “the same *material elements* of fraud” and the first-to-file bar applies “regardless of whether the allegations incorporate somewhat different details.” *U.S. ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1189 (9th Cir. 2001) (emphasis added); *see also U.S. ex rel. LaCorte v. SmithKline Beecham Clinical Labs, Inc.*, 149 F.3d 227, 232-33 (3d Cir. 1998) (first-to-file bar implicated by later suit “alleging the same elements of a fraud”); *U.S. ex rel. Hampton v. Columbia/HCA Healthcare Corp.*, 318 F.3d 214, 217-18 (D.C. Cir. 2003) (barring subsequent suit that alleged “merely variations on the fraud [the first-filed] complaint described”).

Relators here, having filed more than five months after Relator Thomas, allege a fraudulent scheme that is materially identical to the scheme alleged in Thomas’s complaint – (a) an unlawful practice of paying doctors purportedly illegal remuneration (b) in exchange for use of Blackstone products (c) that in turn “cause” the submission of false claims for reimbursement to the government. Indeed, Relators attempt to make some of the same allegations made in *Thomas*. *See, e.g.*, Compl. ¶¶ 61 (regarding Dr. Jordan), 68 (discussing Dr. Lewis).

Further, the fact that Relators here name additional physicians in various locations or recount new details pertaining to the alleged scheme is irrelevant. Although the First Circuit has not addressed this issue directly, other circuits have rejected the notion that claims must be identical to invoke the first-to-file bar. *See Grynberg v. Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1279 (10th Cir. 2004) (reasoning that limiting the first-to-file bar to cases with identical facts “would be contrary to the plain meaning of the statute, which speaks of ‘related’ *qui tam* actions, not identical ones.” (citing 31 U.S.C. § 3730(b)(5))); *see also U.S. ex rel. Capella v. United Techs. Corp.*, No. 3:94-CV-2063, 1999 WL 464536, at \*9 (D. Conn. June 3, 1999) (“section 3730(b)(5) precludes a subsequent relator’s claim that alleges the defendant engaged in

the same type of wrongdoing as that claimed in a prior action, even if the allegations cover a different time period or location within a company”). Relators’ claims are barred.

**B. Relators are Barred by the Public Disclosure Bar from Prosecuting this Declined *Qui Tam*.**

The Court should also dismiss Relators’ Complaint because it is barred by the public disclosure bar of the FCA. Under the FCA, “No court shall have jurisdiction over a [*qui tam*] action ... based upon the public disclosure of allegations or transactions in a criminal, civil or administrative hearing ... unless ... the person bringing the action is an original source of the information.” 31 U.S.C. § 3730(e)(4)(A). Under this bar, a defendant need not show that every fact supporting a relator’s allegations of fraud was publicly disclosed before the relator filed suit. Instead, the defendant must only show that the prior public disclosure was “sufficient to put the government on notice of the likelihood of related fraudulent activity.” *See U.S. ex rel. Gilligan v. Medtronic, Inc.*, 403 F.3d 386, 389 (6th Cir. 2005).

Relators’ central allegation is that Blackstone engaged in a “campaign to induce physicians to utilize its medical products by paying illegal kickbacks.” (Compl. ¶74.) Relators’ Complaint, however, was filed more than *one year* after identical allegations were publicly disclosed in another lawsuit. *Berrios v. Blackstone Medical, Inc.*, Case No. 05-2005-CA-17339 (Brevard Co., Fla.), “*Berrios Compl.*” attached as Exh. A, ¶ 10.) *Berrios*, filed in Florida where Relators live, provided sufficient public disclosure to alert the government to alleged potential fraud at Blackstone.

In *Berrios*, the plaintiff contended that Blackstone “routinely provides incentives to orthopedic surgeons to use their devices over those of their competitors, including, upon information and belief, offering practitioners paid travel and entertainment labeled as ‘continuing medical education’ and paying financial incentives to high-volume users under the guise of

‘consulting’ agreements.” (*Berrios* Compl. ¶10.) Relators’ Complaint actually recycles these allegations and attempts to capitalize on them. *See, e.g., Berrios* Compl. ¶ 10, *Hutcheson* Compl. ¶¶ 32, 34. The FCA seeks to “discourage[e]” exactly this type of “opportunistic behavior” from plaintiffs hoping to profit on information already in the public domain and thus already known or available to the government. *U.S. ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 651 (D.C. Cir. 1994); *see also U.S. ex rel. S. Prawer & Co. v. Fleet Bank of Me.*, 24 F.3d 320, 326 (1st Cir. 1994).

Moreover, Relators’ Complaint acknowledges that government authorities were already aware of allegations of misconduct at Blackstone when they filed suit. The Complaint states that in late summer 2006, St. Dominic’s Hospital in Jackson, Mississippi contacted FBI agents regarding suspicions of kickbacks paid to a doctor by Blackstone. (Compl. ¶ 68.) “[T]he function of a public disclosure is to bring to the attention of the relevant authority that there has been a false claim against the government.” *U.S. ex rel. Feingold v. Administer Fed., Inc.*, 324 F.3d 492, 495 (7th Cir. 2003). Once the government is aware of the fraud, it is “in a position to vindicate society’s interests, and a *qui tam* action would serve no purpose.” *Id.*, *see also U.S. ex rel. Findley v. FPC-Boron Employees’ Club*, 105 F.3d 675, 685 (D.C. Cir. 1997) (noting that once an allegation is public, a *qui tam* suit would “either pressur[e] the government to prosecute cases when it has good reason not to or reduc[e] the government’s ultimate recovery”).

Relators cannot claim to be an “original source” under 31 U.S.C. § 3730(e)(4)(B). The FCA defines an “original source” as someone “who has direct and independent knowledge of the information on which the allegations are based.” 31 U.S.C. § 3730(e)(4)(B). Relators simply declare that they are each original sources. (Compl. ¶ 7 (“Each Relator is an original source of the information upon which this complaint is based ....”)) Conclusory assertions do not suffice -



the public disclosure bar is jurisdictional and Relators bear the burden of pleading facts establishing that the Court has jurisdiction. *See* 31 U.S.C. § 3730(e)(4).

The FCA does not empower or reward Relators who join the chorus. “A whistleblower sounds the alarm; he does not echo it. The Act rewards those brave enough to speak out in the face of a ‘conspiracy of silence,’ and not their mimics.” *U.S. ex rel. Poteet v. Lenke*, No. 07-10237-RGS, 2009 WL 724940, \*2 n.10 (D. Mass. Mar 20, 2009) (internal citations omitted). Thus, Relators’ Complaint here is barred.

**C. Relators’ Complaint Should Be Dismissed for Failure to State a Claim.**

To state a claim under the FCA, Relators must allege: (1) that the defendant presented or caused to be presented to the government, a claim for approval or payment, (2) that claim was false or fraudulent, and (3) the action was undertaken knowingly. *See, e.g., U.S. ex rel. Karvelas*, 360 F.3d at 225. <sup>2/</sup> The FCA “does not create a cause of action against all fraudulent conduct affecting the government. Rather, FCA liability attaches to a ‘false or fraudulent claim for payment’ or to a ‘false record or statement [made] to get a false or fraudulent claim paid’ by the government.” *U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir. 2007) (overruled on other grounds) (internal citations omitted).

Relators do not allege the existence of a false or fraudulent claim. They do not allege that Blackstone knowingly caused the submission of any such claim. And, they do not assert that any

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<sup>2/</sup> To the extent that Relators seek to bring a claim under section 3729(a)(2), the requirements to state a cause of action are slightly different. However, Relators have failed to allege any such claim, let alone with the particularity required by Rule 9(b). *See, e.g. U.S. ex rel. Gagne v. City of Worcester*, No. 08-1904, 2009 WL 1260412, at \*7 n.7 (1<sup>st</sup> Cir. May 8, 2009) (“As to subsection (a)(2) or (a)(3) claims, the relator must still connect the allegedly fraudulent statement to a planned claim on the government fisc, must show that the defendant intended the statement would have a material effect on the government’s decision to pay a claim, and must plead the facts of the fraud with sufficient particularity to satisfy Rule 9(b).”)

alleged fraudulent conduct was material to the government's payment decision. As such, the Complaint fails to state an FCA claim against Blackstone, and should therefore be dismissed.

**1. Relators Have Not Alleged a False or Fraudulent Claim Resulting From Any Alleged Violation of the Federal Anti-Kickback Statute.**

Relators' FCA claim is predicated upon alleged violations of the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b) ("AKS"). Those claims fail as a matter of law because neither Blackstone's allegedly illegal promotion of products, nor its alleged awareness of their use after the promotion, can legally "cause" the submission of a false or fraudulent claim to the government. It is well-settled that "FCA liability does not attach to violations of federal law or regulations ... that are independent of any false claim." *U.S. ex rel. Rost*, 507 F.3d at 727. Rather, Relators must allege more than merely that Blackstone "caused" a hospital to submit a "false claim" to the government.

Courts that have recognized the viability of an FCA claim predicated on an AKS violation have done so under the theory that making a false certification of statutory or regulatory compliance can render a claim "legally false" where compliance with a particular statute or regulation is a condition of reimbursement. *See, e.g., U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997). The Complaint, however, alleges no basis upon which to predicate FCA liability. Consequently, Relators' Complaint must be dismissed as legally deficient.

Although general in nature, one thing is perfectly clear about Relators' allegations in this case – they are factually of a completely different character from any other case in which AKS violations have been held to state a claim for FCA liability. An AKS violation between a medical device manufacturer and a physician does not necessarily cause a hospital to submit a

legally false claim. Hospitals are not required to, and do not, certify that manufacturers or physicians comply with the AKS nor could they reasonably be expected to do so.

In *U.S. ex rel. Thomas*, the Court was presented with the identical facts at issues here, focused its inquiry on whether hospitals, as a condition of receiving payment for medical procedures, impliedly or expressly certified not only to their own compliance with the AKS, but also to the compliance of others. The Court held “that a hospital’s act of submitting a claim for payment to the government impliedly certifie[d] that the hospital has complied with the [AKS] ... [but] they did not impliedly or expressly certify that the physicians who attended patients in their hospital complied with that statute.” *U.S. ex rel. Thomas v. Bailey*, No. 4:06CV00465-JLH, 2008 WL 4853630, at \*9, \*13 (E.D. Ark. Nov. 6, 2008). The Court also found that the hospital’s certification of annual Medicare cost reports did not constitute an express certification that a physician (a non-employee of the hospital) complied with the AKS when selecting surgical devices. The Court found it “impossible that the person signing the cost report could have knowledge” and recognized that it was “difficult to see why the government would require someone to certify to matters that are both beyond his knowledge and beyond what he could possibly know.” *Id.* at \*10. As in *Thomas*, there are no allegations here that any hospital violated the AKS or was aware of any alleged violations by Blackstone or physicians or that the claims submitted for reimbursement involved devices procured in violation of the AKS.

The first-to-file bar is highly instructive of the weight to be afforded the *Thomas* decision in this case. In section 3730(b)(5), Congress recognized that multiple *qui tams* against the same defendant for essentially the same conduct were virtually the same civil lawsuit between the United States and the defendant. The first-to-file doctrine has an important intersection with the law of the case doctrine here. The *Thomas* relator argued that hospital claims in that case should

not be dismissed; his contention was that a hospital could unknowingly submit a false certification even where it did not know about any illegal conduct. The government filed a statement of interest and appeared at oral argument to support this theory. The district court in Arkansas rejected this argument as an unwarranted expansion of the FCA and dismissed the hospital claims. That ruling should apply to the *Hutcheson* complaint, and Blackstone should not be required to re-litigate it: because the two complaints are really a single case, the Arkansas ruling should apply as the law of the case. Under the “law-of-the-case” doctrine, “when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case.” *Naser Jewelers, Inc. v. City of Concord*, 538 F.3d 17, 20 (1st Cir. 2008) (quoting *Ariz. v. Calif.*, 460 U.S. 605, 618 (1983)). Deferring to *Thomas* as the law of the case would allow this Court to “avoid[] the wastefulness, delay, and overall wheel-spinning that attend piecemeal consideration of matters which might have been previously adjudicated.” *U.S. v. Connell*, 6 F.3d 27, 30 (1st Cir. 1993).

Because of the law of the case doctrine, any claim submitted by a hospital for services involving Blackstone products could not be legally false by virtue of an alleged kickback paid by the manufacturer to a physician. The United States, through a relator and on its own behalf has tried, and failed, to establish the viability of this flawed theory of FCA liability.

**2. Blackstone’s Alleged AKS Violations Are Too Attenuated to Satisfy the FCA’s “Knowingly Causing” Requirement.**

Relators’ Complaint also fails because Relators have not alleged facts to establish that Blackstone “knowingly caused” any false claim to be submitted. *See U.S. v. Taber Extrusions, LP*, 341 F.3d 843, 845 (8th Cir. 2003) (interpreting *U.S. ex rel. Marcus v. Hess*, 317 U.S. 537 (1943)). To avoid dismissal, a complaint must allege that (1) Blackstone had knowledge of a plan to cheat the government and (2) that Blackstone committed an affirmative act to cause a

false claim to be submitted. *See U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714-15 (10th Cir. 2006). Relators fail to allege either.

Relators' allegations of knowing causation are general and limited: "BMI knowingly caused the submission of false claims to the United States for spinal surgeries performed on Medicare, Medicaid and other federally-funded patients." (Compl. ¶ 69.) Relators also allege that "Defendants' kickbacks to physicians and others were intended to, and did, cause the submission of false claims ...." (Compl. ¶ 77.) Relators' causation theory is too attenuated as a matter of law. Given the context of those allegations, as recognized in *Thomas*, more is required.

### **3. The AKS Violation Alleged Is Not Material to the Government's Payment Decision.**

A false statement subjecting a person to liability under the FCA must be shown to be material – i.e., that it “has a natural tendency to influence agency action or is capable of influencing agency action.” *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 378 (4th Cir. 2008) (citation omitted); *U.S. ex rel. Gagne v. City of Worcester*, No. 08-1904, 2009 WL 1260412, at \*6 (1<sup>st</sup> Cir. May 8, 2009) (affirming dismissal where relators do not show how alleged fraudulent information had a "material effect on the government's decision to pay...."). Under the FCA, Relators must allege a statement or course of conduct by Blackstone that could have been material to the government's decision to pay a hospital claim under applicable Medicare rules or regulations.

Medicare payments to hospitals are made prospectively at pre-determined rates based upon a patient's diagnosis. 42 C.F.R. § 412.2. Because the hospital is paid a lump sum for the patient's entire episode of care, itemized charges for specific devices would not affect the amount the government reimbursed a hospital for each episode. *See U.S. ex rel. Digiovanni v. St. Joseph's/Candler Health Sys., Inc.*, No. CV 404-190, 2008 WL 395012, at \*6 (S.D. Ga. Feb. 8,

2008) (granting the defendant's motion to dismiss an FCA action alleging that the defendant hospital fraudulently submitted claims to Medicare that included impermissible charges for reusable medical equipment, and noting that "[b]ecause the PPS system pays a standard rate based on the patient diagnosis and the DRG code, the itemized charges on a patient's bill are immaterial to the amount of reimbursement a provider receives[.]"); *U.S. ex rel. Magid v. Wilderman*, No. Civ. A.96-CV-4346, 2004 WL 945153, at \*8-9 (E.D. Pa. Apr. 29, 2004) (granting summary judgment on FCA claims that hospital defendant billed Medicare for lab tests that were not sufficiently documented to warrant reimbursement, and concluding that allegations of overcharging Medicare were unsupported because inpatient services were reimbursed on a DRG basis and laboratory services were similarly subject to a flat "facility fee" reimbursement).

The particular device a surgeon chooses to use, therefore, or the manner in which the surgeon uses it, is immaterial to the Medicare reimbursement decision or amount. Regardless of whether underlying conduct violates the AKS, the FCA does not provide the United States a remedy absent material falsity.<sup>3/</sup> Even if Relators could plead that Blackstone knowingly caused the submission of a claim through kickbacks paid to physicians, which they cannot, Relators still could not show that such conduct caused the submission of a claim that was false in a material manner.

**D. The Complaint Should Be Dismissed for Failure to Plead Alleged Kickbacks and Resultant False Claims with the Particularity Required under Rule 9(b).**

Rule 9(b) applies to complaints for violations of the FCA. *U.S. ex rel. Karvelas*, 360 F.3d at 228. Rule 9(b) requires that "[i]n all averments of fraud or mistake, the circumstances

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<sup>3/</sup> Relators allege that hospitals submit "patient-specific claims for interim payments on a Form UB-92." Compl. ¶ 26. Notably, Relators do not allege that a Form UB-92, also referred to as CMS Form 1450, requires identification of any device or manufacturer.

constituting fraud or mistake shall be stated with particularity.” Fed. R. Civ. P. 9(b). Failure to meet these requirements of Rule 9(b) is treated as a failure to state a claim under Rule 12(b)(6).

Among the purposes served by Rule 9(b) are that specificity ensures that the defendant is put on notice of the conduct complained of such that it can formulate a defense; and discourages plaintiffs from filing allegations of fraud merely in hopes of conducting embarrassing and costly discovery and forcing settlement. *Rost*, 507 F. 3d at 733. These concerns are especially acute in *qui tam* suits, such as this one, where Relators have made sweeping allegations of nationwide fraud, purportedly involving an untold number of hospitals and physicians over an unknown period of time and as to which they claim no first-hand knowledge of the hospitals’ certifications or claims.

To satisfy Rule 9(b), Relators must plead, at a minimum, the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby. *Id.* at 732. Relators must allege the who, what, when, where, and how of the alleged fraud. *U.S. ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147 (D. Mass. 2000). Moreover, because the submission of a false claim is the *sine qua non* of a FCA violation, a relator must plead not only the underlying fraud with specificity, but also must “provide details that identify particular false claims for payment that were submitted to the government.” *Rost*, 507 F.3d at 731 (quoting *Karvelas*, 360 F.3d at 232). While Relators can satisfy Rule 9(b) even though some questions remain unanswered, the complaint as a whole must be sufficiently particular as to pass muster under the FCA. *Id.* at 732. *Qui tam* relators cannot rely on non-particularized allegations, as they have here, “in the hope . . . details will emerge through subsequent discovery.” *Id.* (internal quotation marks and citation omitted).

Again, FCA liability attaches only to false claims, not merely to underlying fraudulent activity. *Id.* Here the bulk of Relators' allegations relate to then purportedly underlying fraudulent activity - unlawful kickbacks. Violations of the AKS, however, are not actionable by Relators; evidence of actual false claims is needed to maintain an FCA action. *See, e.g., W. Allis Mem'l Hosp., Inc. v. Bowen*, 852 F.2d 251, 255 (7th Cir. 1988) (the AKS does not provide for a private right of action); *Rost*, 507 F.3d at 732. Indeed, the *Rost* Court dismissed a complaint because it did not "sufficiently establish that false claims were submitted for government payment...." 507 F.3d at 733. The Court explained that while the complaint "amply describe[d] illegal practices in which [the defendant] allegedly engaged....those practices, while illegal, are not a sufficient basis for an FCA action because they do not involve claims for government reimbursement," and "[a]t most, [the relator] raised facts that suggest fraud was possible; but the complaint contained no factual or statistical evidence to strengthen the inference of fraud beyond possibility." *Id.* at 732-33.

Relators' Complaint in this case has even worse defects than the *Rost* complaint. Relators' allegations of false claims that supposedly flowed from alleged "kickbacks" to physicians are deficient because the Complaint does not contain allegations substantiating that actual false claims were submitted. *U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 551 F. Supp. 2d 100, 115 (D. Mass. 2008) (finding that relator failed to satisfy Rule 9(b) even though he identifies discounts, rebates and educational grants paid to providers because "he fails to identify a single false claim consequently filed by these providers.").

In the language of Rule 9(b), the defect is critical here, where no defendant has in its possession any actual Medicare claims, because Relators have failed to allege even the "who" for whose claims Relators would hold Defendants liable. Relators fail to identify even one single



false claim that allegedly resulted from Defendants' actions. Relators do not provide the name of one single hospital where a physician that allegedly received kickbacks from Blackstone conducted a surgery for which a federal claim was submitted.<sup>4/</sup> Nor do Relators identify the location of the fraud or even the time period in which it occurred.<sup>5/</sup>

Relators provide a single conclusory allegation that "[t]he scheme to cause the filing of false claims described herein was pervasive and nationwide and took place for many years." (Compl. ¶ 71.) This bare allegation alone is totally insufficient to allege a nationwide fraud spanning many years. *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 538 F. Supp. 2d 367, 391 (D. Mass. 2008) (limiting complaint to the years and region in which the plaintiff worked and for which plaintiff provided examples that identified particular time, doctors and hospitals and circumstances of alleged scheme).<sup>6/</sup>

#### **E. Relators' Conspiracy Claim Fails to Allege Essential Elements.**

Relators' fleeting one-paragraph reference to a Blackstone-led conspiracy to defraud the government suffers from the same Rule 9(b) defect as their other FCA claims, and should be dismissed on that basis. *U.S. ex rel. Gagne*, 2009 WL 1260412, at \* 4 (Rule 9(b) requirements apply to conspiracy claims). The FCA imposes liability on those who "conspire[ ] to defraud the government by getting a false ... claim allowed or paid." 31 U.S.C. § 3729(a)(3). To assert a

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<sup>4/</sup> Relators are able to identify a single hospital by name. The allegations regarding this hospital are not based on first-hand information and are learned eight months after Relator Hutcheson signed a release waiving all claims against Blackstone. As discussed above, the allegations suggest this Court might lack jurisdiction as a result of the public disclosure bar.

<sup>5/</sup> Although Relators generally refer to cost reports, such general references to template forms are insufficient to satisfy Rule 9(b). *U.S. ex rel. Duxbury*, 551 F. Supp. 2d at 116 (The mere identification of the template forms which providers used to submit reimbursement is insufficient when not tied to a particular claim filed by a particular provider.)

<sup>6/</sup> Relators also fail to allege specific instances of fraud under the AKS. For example, they do not tie a specific payment to a specific order and do not identify specific payments made to specific physicians in exchange for purchases.

claim under Section 3729(a)(3), Relators must allege that the conspirators agreed to defraud the government by making or causing to be made a false record that would have a material effect on the government's decision to pay a false claim. *See Allison Engine Co. v. U.S. ex rel. Sanders*, 128 S. Ct. 2123, 2130 (2008).

Relators allege only that "Defendants conspired with others, to include physicians who accepted kickbacks, to defraud the United States by getting false claims allowed and paid." (Compl. ¶ 78.) They do not describe an agreement, its parties, or any overt acts taken in furtherance of the agreement. *See U.S. ex rel. Carroll v. JFK Med. Ctr.*, No. 01-8158-CIV, 2002 WL 31941007, at \*5 (S.D. Fla. Nov. 15, 2002) (dismissing complaint that presented "no factual basis for its allegation that Defendants entered into a conspiracy to defraud the government" and provided no allegation of an agreement); *U.S. ex rel. Capella v. Norden Sys., Inc.*, No. 3-94-CV-2063(EBB), 2000 WL 1336487, at \*11 (D. Conn. Aug. 24, 2000) (dismissing FCA conspiracy claim under Rule 9(b) where the complaint "merely alludes to an agreement between Defendants and does not specify the particulars of how and when that alleged conspiracy arose, who entered into it, or what act was committed in furtherance of the conspiracy"). Relators' conspiracy claims should be dismissed.<sup>7/</sup>

**F. Plaintiff Hutcheson Does Not Allege the Elements of a Retaliatory Discharge Claim under the FCA.**

Count II of the Complaint, the FCA retaliatory discharge claim brought by Hutcheson, should be dismissed because she fails to allege essential elements of a cause of action under that provision. The FCA prohibits retaliation against an employee who engages in activity protected by the FCA, i.e., "lawful acts done by the employee, on behalf of the employee or others in

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<sup>7/</sup> With respect to the indicia of their worthiness as Relators, Hutcheson's allegations at least purport to reflect her own limited personal knowledge – even though most was allegedly gained from others after her employment with Blackstone was terminated. There are no allegations in the Complaint, however, with respect to Brown's personal knowledge.

furtherance of an action under this section, including investigation for, initiation of, ... or assistance in an action filed or to be filed under this section....” 31 U.S.C. § 3730(h). To prevail, a plaintiff must show (1) that she was engaged in conduct protected under the FCA, (2) that her employer knew about the protected activity, and (3) that the employer discharged or discriminated against her because of the protected activity. *Maturi v. McLaughlin Research Corp.*, 413 F.3d 166, 172 (1st Cir. 2005).

Hutcheson does not allege any of these elements. According to the Complaint:

Relator Hutcheson repeatedly questioned her supervisors about BMI’s business practices, including whether BMI was buying the business of physicians. She also objected to other practices at BMI, including the policy and practice of entertaining the physicians in whatever manner they requested . . . . Relator Hutcheson refused to entertain the physicians in this manner. As a result, Relator Hutcheson was wrongfully discharged in January 2006.

(Compl. ¶ 82.) Nowhere does Hutcheson allege that when she “questioned her supervisors” she claimed that Blackstone’s business practices were illegal or that Blackstone was committing fraud on the government.

Hutcheson also fails to allege how her repeated questioning resulted in her termination, the third element of a retaliation claim. *U.S. ex rel. Karvelas*, 360 F.3d at 240 (dismissing retaliation count because plaintiff failed to allege a concrete factual nexus between his protected conduct and retaliation). Hutcheson does not allege that that she was fired for raising her concerns but rather for refusing to entertain physicians by acting provocatively with male physicians. Notably, however, the Complaint provides only a single example of such entertainment and it was learned by Hutcheson months after she left Blackstone. (Compl. ¶¶ 64, 82.) Even when Rule 9(b) does not come into play, some pleading threshold does exist, and plaintiffs are prohibited from relying upon vague or conclusory allegations. *U.S. ex rel. Karvelas*, 360 F.3d at 240 (“[s]imply parroting the language of a statutory cause of action, without

providing some factual support, is not sufficient to state a claim.”). Conclusory allegations aside, Hutcheson’s *factual* allegations do not establish a colorable claim of retaliation, and therefore Count II should be dismissed.

**G. Plaintiff Hutcheson Waived Her Right to Bring a Retaliation Claim.**

On or about January 3, 2006, Plaintiff Hutcheson signed a release waiving all known and unknown claims she had against Blackstone. (Exh. B. at ¶ 4). Regardless of the potential effect of that release on her right to serve as a Relator, that release controls to extinguish any claim she had for retaliation under Section 3730(h). *Cf. U.S. ex rel Summit v. Michael Baker Corp.*, 40 F. Supp. 2d 772 (E.D. Va. 1999) (holding a relator can settle a retaliatory discharge claim independent of his FCA claim).<sup>8/</sup>

**CONCLUSION**

For all of the foregoing reasons, Defendant Blackstone requests that the Court grant this motion to dismiss, with prejudice, and dismiss Relators’ Complaint in its entirety.

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<sup>8/</sup> Blackstone specifically reserves its right to seek dismissal of any portion of Relator Hutcheson’s *qui tam* claims, should any survive this motion, on the basis of this release at a later date.

Respectfully submitted,

Dated: May 14, 2009

By: /s/ Brien T. O'Connor

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**CERTIFICATE OF SERVICE**

I hereby certify that these documents filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non registered participants on May 14, 2009.

Dated: May 14, 2009

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